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EXAMINER	
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1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,652	MURATOGLU ET AL.	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *2,87,90-93,101,103,109 and 110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/09, 2/13/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,7,8,11-14,22-24,26,29,30,32,36-39,60,62-64,67,72,74,76,78,80-87,90-101,103, and 105-124.

Continuation of Disposition of Claims: Claims rejected are 1,3,7,8,11-14,22-24,26,29,30,32,36-39,60,62-64,67,72,74,76,78,80-86,94-100,105-108 and 111-124.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species A {claims 1, 3, 7-8, 11-14, 22-24, 26, 29-30, 32, 36-39, 60, 62-64, 72, 74, 76, 78, 80-86, 94, 95, 97, 105, 107, and 111-112 in the reply filed on 1/16/09 is acknowledged. Claims 67, 96, 98-100, 106, 108, and 113-124 are grouped with Species A.

Claims 4, 58-59, 61, 65-66, 68-71, 73, 75, 77, 79, 88, 89, 102 and 104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/16/09.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 7-8, 11-14, 22-24, 26, 29-30, 32, 36-39, 60, 62-64, 67, 72, 74, 76, 78, 80-86, 94-100, 105-108, and 111-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: doping the polymeric material with an antioxidant (to afford an antioxidant-doped polymeric material}. Accordingly dependent claim 24 is indefinite.

Regarding claim 32, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claims 1, 3, 7-8, 11-14, 22-24, 26, 29-30, 32, 36-39, 60, 62-64, 67, 72, 74, 76, 78, 80-86, 94-100, 105-108, and 111-112, the phrase "at least 10-1000 MPa" renders the claim(s) indefinite because it is unclear if the pressure is at least 10 MPa, at least 1000 MPa, or a range of 10-1000 MPa thereby rendering the scope of the claim(s) unascertainable. Accordingly dependent claims 3, 7-8, 11-14, 22-24, 26, 29-30, 32, 36-39, 60, 62-64, 67, 72, 74, 76, 78, 81-86, 96, 98, 100 and 106, 108 are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 99-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Saum *et al.* (US 2002/0107300).

Regarding claim 99: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising annealing UHMWPE in nitrogen {blending with an additive} (¶47); irradiating UHMWPE rod with

gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Regarding claim 100: Saum *et al.* teaches preferred pressures of 230 MPa to 480 MPa, as well as greater than 310 MPa (¶ 18); with a preferred embodiment having a pressure of about 345 MPa (¶ 41).

Claims 105-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Mckellop *et al.* (WO 99/52474).

Regarding claims 105-106: Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21), wherein bearing surfaces {acetabular cup} [instant claim 106] (pg. 10, ln. 21-32) are prepared by blending UHMWPE with peroxide (11:3-12); contacting the UHMWPE/peroxide blend with a preformed UHMWPE cup {bearing); compression molding UHMWPE and UHMWPE/peroxide blend at 2000 psi (~ 14 MPA}, heating to a temperature of 170 °C for 2 h, then slow cooled to RT at 2000 psi (pg. 36, ln. 31-pg. 37, ln. 21; pg. 40, ln. 5-36). Mckellop *et al.* teaches surface crosslinking acetabular cups via irradiating below or above the melt of UHMWPE (pg. 15, ln. 15-18; pg. 20, ln. 1-2); after chemical crosslinking (pg. 26, ln. 18-24).

Claims 112 is rejected under 35 U.S.C. 102(b) as being anticipated by Mckellop *et al.* (WO 99/52474).

Regarding claim 112: Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21), wherein bearing surfaces {acetabular cup} (pg. 10, ln. 21-32) are prepared by blending UHMWPE with peroxide (11:3-12); contacting the UHMWPE/peroxide blend with a preformed UHMWPE cup {bearing); compression molding UHMWPE and UHMWPE/peroxide blend at 2000 psi (~ 14 MPA}, heating to a temperature of 170 °C for 2 h, then slow cooled to RT at 2000 psi (pg. 36, ln. 31-pg. 37, ln. 21; pg. 40, ln. 5-36). Mckellop *et al.* teaches surface crosslinking acetabular cups via irradiating above the melt of UHMWPE (pg. pg. 20, ln. 1-2); after chemical crosslinking (pg. 26, ln. 18-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7, 29-30, 32, 36-39, 60, 72, 74, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300).

Regarding claim 1: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 1}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Regarding claim 3: Saum *et al.* teaches heating to about 200 °C (while the vessel is at 220 °C) (¶ 18).

Regarding claim 7: Saum *et al.* teaches preferred pressures of 230 MPa to 480 MPa, as well as greater than 310 MPa (¶ 18); with a preferred embodiment having a pressure of about 345 MPa (¶ 41).

Regarding claims 29-30 and 32: Saum *et al.* teaches ultrahigh molecular weight polyethylene (UHMWPE) [instant claims 29-30] (¶ 9, 11-12), which were rod shaped [instant claims 32] (¶ 36, 40-41).

Regarding claims 36-38: Saum *et al.* teaches gamma rays (¶ 36, 40-41) in a dose of 0.5-10 Mrad, specifically 0.5, 1, 2, and 5 Mrad {0.5-10 Mrad = 5-100 kGy} (¶ 13-14, 40-41).

Regarding claim 39: Saum *et al.* teaches electron beam (¶ 13).

Regarding claim 60: Saum *et al.* teaches medical implants, with a preferred use as a bearing surface (¶ 20).

Regarding claim 72, 74, and 76: Saum *et al.* teaches irradiating at RT [instant claim 72] (¶ 37, 41). Saum *et al.* discloses heating the irradiated preform at or above the onset of melting (¶ 17).

Saum *et al.* does not specifically teach the irradiation step at or above the onset of melting [instant claim 74 and 76]. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300).

Regarding claim 97: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising annealing UHMWPE in nitrogen {blending with an additive} (¶47); irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 97}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300).

Regarding claim 111: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising annealing UHMWPE in nitrogen {blending with an additive} (¶47); irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated

UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 111}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Claims 8, 11-14, 22-24, 62-64, 67, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) as applied to claim 1 above, and further in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 8, 11-14, 22-24, 26, 62-64, 67, and 78: Saum *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 1].

Saum *et al.* does not teach doping UHMWPE with an antioxidant via diffusion doping [instant claims 8 and 22]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant (abstract) via diffusion doping {supercritical CO_2} (4:46-5:11); annealing the doped polymer at a temperature above 80 °C; mechanically processing the polymer {machining/mechanically deforming} [instant claims 11-13, 23, 63] (5:65-6:18; 7:1-15); medial implants obtained from the doped polymer [instant claim 64] (3:30-36; 5:66-6:7); and packaging the sterilized implant {γ-

radiation} (4:15-45; 6:1-7) [instant claims 13-14, 62]; wherein the radiation/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18) [instant claim 67, 78]. Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2} and annealing, packing, and sterilization, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Regarding claim 26: Saum *et al.* teaches medical implants, with a preferred use as a bearing surface (¶ 20).

Claims 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 80-86: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach blending with an additive and consolidating the blend [instant claim 80]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically

vitamin E [instant claims 83-84] (abstract, 1:5-11) in an amount of 0.005 -5 wt% [instant claims 85-86] (3:63-65) via diffusion doping {supercritical CO_2} {blending with an additive} (4:46-5:11); compression molding the UHMWPE/antioxidant blend {consolidating} [instant claim 80] (5:65-6:7); annealing the doped polymer at a temperature above 80 °C; mechanically processing the polymer {machining/mechanically deforming} (5:65-6:18; 7:1-15); medial implants obtained from the doped polymer [instant claim 82] (3:30-36; 5:66-6:7); and packaging the sterilized implant {γ-radiation} (4:15-45; 6:1-7) [instant claim 81]; wherein the radiation/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2} and annealing, packing, and sterilization, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claim 94: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C;

pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 94}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach blending with an additive and consolidating the blend [instant claim 94]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an additive} (4:46-5:11); compression molding the UHMWPE/antioxidant blend {consolidating} [instant claim 94] (5:65-6:7) wherein radiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2} and compression molding, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants

provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claim 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 95-96: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C [instant claim 96]; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 95}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach blending with an additive and consolidating the blend [instant claim 95]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically vitamin E (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an additive}

(4:46-5:11); annealing the doped polymer at a temperature above 80 °C ; wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2} and annealing, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claims 97-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 97-98: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 97}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See

also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach blending with an additive and consolidating the blend [instant claim 97]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically vitamin E [instant claims 98] (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an additive} (4:46-5:11); annealing the doped polymer at a temperature above 80 °C; wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2}, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claims 99-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 99-100: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising

irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach blending with an additive and consolidating the blend [instant claim 99]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically vitamin E (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an additive} (4:46-5:11); annealing the doped polymer at a temperature above 80 °C; wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2}, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Regarding claim 100: Saum *et al.* teaches preferred pressures of 230 MPa to 480 MPa, as well as greater than 310 MPa (¶ 18); with a preferred embodiment having a pressure of about 345 MPa (¶ 41).

Claim 107-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 107-108: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays (¶ 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 107}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach annealing at a temp below the melt after irradiation and mechanically deformation [instant claim 107]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant (abstract, 1:5-11) (3:63-65) via diffusion doping {supercritical CO_2} {blending with an additive} (4:46-5:11); compression molding the UHMWPE/antioxidant blend {consolidating} (5:65-6:7); annealing the doped polymer at a temperature above 80 °C [instant claim 107]; mechanically processing the polymer {machining/mechanically deforming} [instant claim 108] (5:65-6:18; 7:1-15); wherein the radiation/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the

preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2} annealing, and molding/machining, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants and annealed provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claims 113 and 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315).

Regarding claims 113 and 115: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays at RT [instant claim 115] (¶ 14, 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 113}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In*

re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach blending with an antioxidant and consolidating the blend [instant claim 113]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically vitamin E (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an antioxidant} (4:46-5:11); compression molding the UHMWPE/antioxidant blend {consolidating} [instant claim 113] (5:65-6:7); annealing the doped polymer at a temperature above 80 °C; mechanically processing the polymer {machining/mechanically deforming} (5:65-6:18; 7:1-15); wherein the radiation/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2}, consolidation, and annealing, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Claim 114 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315), and in view of Mckellop *et al.* (WO 99/52474)..

Regarding claim 114: Saum *et al.* teaches a method of making a crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) (abstract, ¶ 9) comprising irradiating UHMWPE rod with gamma rays at RT (¶ 14, 36, 40-41); heating the irradiated UHMPE to 250 °C; pressurizing the heated UHMWPE to 50,000 psi {~345 MPa}; maintaining 250 °C and 50,000 psi for 1-2 h; cooling to 75 °C; and releasing the pressure (¶ 18-20, 36, 40-41).

Saum *et al.* does not teach the irradiation step after the heating/pressurization process {Saum *et al.* does not teach process steps in the same order of instant claim 114}. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Saum *et al.* does not teach blending with an antioxidant and consolidating the blend [instant claim 114]. However, Lidgren *et al.* teaches UHMPE doped with an antioxidant, specifically vitamin E (abstract, 1:5-11) via diffusion doping {supercritical CO_2} {blending with an antioxidant} (4:46-5:11); compression molding the UHMWPE/antioxidant blend {consolidating} [instant claim 113] (5:65-6:7); annealing the doped polymer at a temperature above 80 °C; mechanically processing the polymer {machining/mechanically deforming} (5:65-6:18; 7:1-15); wherein the radiation/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Saum *et al.* and Lidgren *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the

preparation UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined antioxidant {vitamin E} via diffusion doping {supercritical CO_2}, consolidation, and annealing, as taught by Lidgren *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Lidgren *et al.* suggests that UHMWPE doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18).

Saum *et al.* does not teach irradiating at a temperature of above the melting point of UHMWPE [instant claim 114] However, Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature above the melt [instant claims 114] (pg. 20, ln. 1-2) {note $T_{m\,peak}$ of UHMWPE ~135 °C}. Saum *et al.* and Mckellop *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined irradiating at a temperature above the melt (pg. 20, ln. 1-2), as taught by Mckellop *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Mckellop *et al.* suggests that irradiated at a temperature above the melt provides a desired maximum crosslinking in the surface layer and a ate of decrease below his layer, in order to get the required improvement in wear resistance in a surface layer of desired thickness (pg. 20, ln. 1-15).

Claim 116-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum *et al.* (US 2002/0107300) in view of Lidgren *et al.* (US 6,448,315), as applied to claim 113 above, and further in view of Mckellop *et al.* (WO 99/52474)..

Regarding claims 116-124: Saum *et al.* and Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 113].

Saum *et al.* does not teach irradiating at a temperature of about: 90 °C [instant claim 116]; 100 °C [instant claim 117]; 110 °C [instant claim 118]; 120 °C [instant claim 119]; 130 °C [instant claim 120]; 135 °C [instant claim 121]; 140 °C [instant claim 122]; 145 °C [instant claim 123]; and 150 °C [instant claim 124] However, Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature below the melt [instant claims 116-120] (pg. 15, ln. 15-18); or at a temperature above the melt [instant claims 121-124] (pg. 20, ln. 1-2) {note $T_{m\,peak}$ of UHMWPE ~135 °C}. Saum *et al.* and Mckellop *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined) irradiated at a temperature below the melt (pg. 15, ln. 15-18); or at a temperature above the melt (pg. 20, ln. 1-2), as taught by Mckellop *et al.* in the invention of Saum *et al.*, and would have been motivated to do so since Mckellop *et al.* suggests that irradiated at a temperature below the melt provides surface crosslinking (pg. 15, ln. 15-18); or at a temperature above the melt which provides a desired maximum crosslinking in the surface layer and a ate of decrease below his layer, in order to get the required improvement in wear resistance in a surface layer of desired thickness (pg. 20, ln. 1-15).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 8, 63, and 95-98 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8, 10, 14, and 16 of copending Application No. 11/15/06. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method steps substantially overlap in scope. While the instant application and '509 do not do the claimed steps in order, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin* , 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*); In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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